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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,123	10/20/2000	Michael C. Barney	661005.90268	7800
26710	7590	08/11/2005	EXAMINER	
QUARLES & BRADY LLP 411 E. WISCONSIN AVENUE SUITE 2040 MILWAUKEE, WI 53202-4497			GHALI, ISIS A D	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/693,123

Applicant(s)

BARNEY ET AL.

Examiner

Isis Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-4 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged if applicants' amendment filed 06/21/2005.

Claims 1-4 are included in the prosecution.

Claim Rejections - 35 USC § 103

1. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,548,552 ('552) in view of US 6,313,178 ('178).

US '552 teaches an absorbent article having additives in a sufficient amount that reduce the toxic shock syndrome toxin production (abstract). The additives are applied to the surface of the absorbent article then dried (col.3, lines 11-20). The absorbent article can be any absorbent article where reduction in toxic shock syndrome toxin production might be beneficial (col.9, lines 50-51).

US '552 does not teach the use of hexahydrolupulone or tetrahydroisohumulone in particular to treat toxic shock syndrome.

US '178 teaches a composition and method for inhibiting the *Staphylococcus aureus* growth. The method comprises contacting the bacteria with an effective amount of hexahydrolupulone (hexahydro-beta acid) or tetrahydroisohumulone (tetrahydroiso-alpha acid). The composition is formulated in an aqueous base water, alcohol, propylene glycol or glycerin. The composition is suitable for topical administration to the

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epidermis (abstract; col.1, lines 30-35; col.2, lines 1-57; col.3, lines 57-62; col.4, lines 63-67; col.5, lines 42, 54-57; col.7, lines 25-29). The hexahydrolupulone and tetrahydroisohumulone are particularly effective against gram-positive bacteria such as *Staphylococcus aureus* (col.2, lines 10-15).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a dry absorbent article that has additives to treat toxic shock syndrome applied to its surface as disclosed by US '552, and replace the additives that treat toxic shock syndrome by hexahydrolupulone or tetrahydroisohumulone as disclosed by US '178, motivated by the teaching of US '178 that hexahydrolupulone or tetrahydroisohumulone are particularly effective against gram positive bacteria such as *Staphylococcus aureus*, with reasonable expectation of having a dry absorbent article with hexahydrolupulone or tetrahydroisohumulone on its surface to inhibit the growth of *Staphylococcus aureus* infection, and consequently, controlling toxic shock syndrome with success.

Response to Arguments

2. Applicant's arguments filed 06/21/2005 have been fully considered but they are not persuasive.

Applicants traverse the obviousness rejection of claim 1-4 over the teachings of US '552 and US '178 by arguing that the combination of the references can not establish a *prima facie* case of obviousness because US '552 teaches agents to reduce TSST production without affecting the growth of normal vaginal flora such as

Staphylococcus species. US '178 does not provide suggestion to modify US '552 that teaches limiting toxin production without affecting the growth of bacteria such as *Staphylococcus* species because US '178 teaches inhibition of the growth of *Staphylococcus aureus*.

In response to the above argument, the examiner is pointing out to the fact that *Staphylococcus* species, and specifically *Staphylococcus aureus*, are not normal vaginal flora; alternatively, they are pathogenic bacteria that causes TSST if present in vaginal tampon or perineum area of infants through the diaper. Therefore, the main purpose of US '552 is to inhibit TSST that is caused by *Staphylococcus aureus* as desired by applicant. US '552 did that by applying an inhibitory agent to *Staphylococcus aureus* into a personal care product, and that what applicants have done for the same purpose. However, US '552 used specific amount that does not affect the normal beneficial vaginal flora. US '178 is relied upon for the solely teaching of specific acids that inhibit the *Staphylococcus aureus*. Therefore, in the opinion of the examiner, the only difference between the combined teaching of the cited prior art and the present invention is the claimed amount, which would only take routine experimentation to optimize. In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination

or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious over the combined teachings of US '552 and US '178 and within the meaning of 35 U.S.C. 103 (a).

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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